[redacted]

PMN No P-18-0107

ChemName: - [redacted]

CASNo: - [redacted]

[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

SAT Date: - 02/13/18
SAT Chair: Doritza Pagan-Rodriguez
HH Hazard Assessor (A): - Keith Salazar
HH Hazard QC Reviewer (A): - William Irwin
HH Hazard QC Date (A): - 2-15-18
Focus Date: 02-22-18
HH Risk Assessor (B): Keith Salazar
HH Risk QC Reviewer (B): - K Jacobs
HH Risk QC Date (B): - 2/21/18

[redacted]

1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard.
Based on the hazard determination and available quantitative risk information, EPA concludes that there is risk for the PMN substance.

Human Health Hazard:

- Absorption of the neat PMN material is nil all routes. The low molecular weight fractions are expected to be poorly absorbed all routes (pchem).
- For the poorly absorbed polymer species with a MW < 500 and for potential metabolites of the absorbed fraction with a MW between 500 and 1000, there is concern for systemic toxicity and developmental toxicity based on data for an analogue.

Human Health Risk:

- Risks were identified for workers for reproductive/developmental and systemic effects via inhalation and dermal exposures based on quantitative hazard analogue data for the LMW fraction (inhalationMOE= 3.4, dermalMOE=0.8; Benchmark MOE = 100).
    - Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves and a respirator (Fold Factor = 30).
- Risks were not identified for the general population for reproductive/developmental and systemic effects via inhalation exposures based on quantitative hazard analogue data for the LMW fraction (MOE = 15,600; Benchmark MOE = 100).
- Risks were not identified for the general population for reproductive/developmental effects via drinking water exposure based on quantitative hazard analogue data for the LMW fraction (adultMOE =5770; infantMOE=1370; Benchmark MOE = 100)
- Risks to consumers were not evaluated because consumer uses were not identified as conditions of use

Potentially Useful Information:

- Reproductive/developmental toxicity

2 HUMAN HEALTH HAZARD- PART A

[redacted]

2.1 Chemistry Summary:

PMN: P-18-0107	Submitter: Lanxess Corporation		Manu.	Import
Max. PV (KG): [redacted]	Binding Option Marked:			X
MW: [redacted]	% < 500 [redacted]	% <1000	CASN [redacted]	

PMN Structure	Prop.	Meas.	Est.
[redacted]	MP	60 - 90	
	BP		>400
	Pres.		at 760 mm Hg
	VP		<0.000001
	S-H2O		<0.000001
	log P		

[redacted]

Analogs: [redacted]

USE:
Hydrolysis stabilizer for polyester and polyamide plastics, mainly poly(lactic acid). The carbodiimide groups react with any terminal acid groups on the polymer chains, acting to decrease further hydrolysis and increase plastic durability.
Carbodiimide FGEW = 315, based on charge.

[redacted]

2.2 Human Health Category:

1. **Chemical Category: not applicable**
2. **Chemical Category Health Concerns:**
3. **Category Testing Strategy:**

2.3 SAT Summary:

2.3.1 Absorption:

Absorption of the neat PMN material is nil all routes. The low molecular weight fractions are expected to be poorly absorbed all routes (pchem).

2.3.2 SAT Health Summary:

For the poorly absorbed polymer species with a MW < 500 and for potential metabolites of the absorbed fraction with a MW between 500 and 1000, there is concern for systemic toxicity and developmental toxicity based on data for an analogue [redacted]

[redacted]

2.3.3 PMN Data:

None provided

2.3.4 Analogue Data:

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(38) ANALOGS:			
PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
[redacted]			

[redacted]

- Health Summary: Absorption of the neat solid will be nil all routes, absorption of low molecular weight fraction is expected to be poor all routs based on physical/chemical properties. No significant health concern. Low concern.

[redacted]

[redacted]

- HEALTH: Absorption of the NEAT solid will be nil all routes, but dissolved in a solvent will be poor all routes based on analogues; possible dehydrating effect and coupling with acids and alcohols but unlikely due to very low water solubility and high MW no significant effects expected; low concern,

[redacted]

[redacted] was dropped from further review. Concerns for potential risks to human health and the environment were low. This was a CEB D1 drop.

[redacted]

This study, [redacted] was administered in corn oil by gavage to groups of 12 male and 12 female HsdRCCHan:Wist rats at doses of 0, 1, 3 or 8 mg/kg body weight. However, based on the pronounced toxicity (statistically significant reduction in body weight reduced produced in the high dose group, the animals of both sexes were not dosed on days 1 and 10. The treatment in these animals was reinitiated on day 11 but at a dose of 5 mg/kg throughout the remainder of the exposure. [*The trade name of this substance is [redacted] No relevant differences were noted up to 3 mg/kg b.w. in the number of corpora lutea or number of animals with and without implantation sites. No corpora lutea or implantation sites were found in any of the animals in the high dose group. At the 1 and 3 mg/kg b.w. dose levels, no treatment-related findings were observed in fertility, gestation indices, mean duration of gestation or number of females with live born pups. Insemination was slightly reduced in the high dose rats while fertility and gestation were severely affected. No gestation were noted in this group. Up to 3 mg/kg b.w., no treatment related effects were observed in the total number of pups born, stillborn pups, live birth index, percentage of males born, litter size at birth and viability index. No macroscopic alterations with a remarkable incidence or dose-dependency were observed at pup necropsies. The evaluation of all the study data resulted in the following determination: F0 rats NOAEL =

[redacted]

3 mg/kg-bw Reproduction/Developmental Toxicity NOAEL: 1 mg/kg-bw (due to slight decrease in prenatal losses at 3 mg/kg-bw)

From ECHA Database:

- OECD TG 407; Wistar rats dosed with 0, 1,4 or 16 mg/kg-d.
  - ALT, ALP increased at 16 mg/kg
  - Increased glucose and cholesterol
  - Increase protein and albumin in blood
  - Reduced kidney weight
  - NOAEL of 4 mg/kg based on effects on heart, liver, kidney, WBC, GI and female genital tract.

2.3.5 Other Information: (SDS, structural alert or component of interest, basis, etc.)

No relevant information (mixture)

2.3.6 Exposure Routes of Interest:

Route of Interest	
x	Inhalation:
x	Dermal:
x	Ingestion:

2.4 Point of Departure Selected and Basis

2.4.1 POD for all routes of exposure

1. **POD type (NOAEL/LOAEL) -** NOAEL
2. **POD Chemical: -** [redacted]
3. **POD Route: -** Oral
4. **POD Endpoint: -** Developmental toxicity
5. **POD Value: -** 1 mg/kg/d
6. **POD Basis: -** Lowest POD
7. **POD Benchmark MOE: -** 100
8. **Reference: -** Submitted data for 8e

2.5 USES and EXPOSURES:

2.5.1 Uses

Hydrolysis stabilizer for polyester and polyamide plastics, mainly poly(lactic acid). The carbodiimide groups react with any terminal acid groups on the polymer chains, acting to decrease further hydrolysis and increase plastic durability.

2.5.2 Worker Exposure

2.5.2.1 Inhalation

Potential Dose Rate: 1.1E+2 mg/day over [redacted] days/yr

2.5.2.2 Dermal

Potential Dose Rate: 3.1E+3 mg/day over [redacted] days/yr (Solid) Unloading Solid Raw Material from Transport Containers

2.5.3 General Population Exposure:

2.5.3.1 Drinking Water:

Drinking water ingestion with ADR as high as 5.70E-04 mg/kg/day

2.5.3.2 Fish:

No measurable exposure estimate

2.5.3.3 Air/Inhalation

Inhalation from fugitive air releases with ADR as high as 2.11-04 mg/kg/day

2.5.4 Consumer Exposure

No identified consumer exposures

2.6 RISK CALCULATIONS:

2.6.1 Worker Calculations:

[redacted]

	Animal or Human			Human							Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/day Potential Dose Rate (PDR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Body Weight kg	Exposure mg/kg-day	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Inhalation	1.0E+00	5	100%	1.1E+02	5	100%	80	1.4E+00	22%	**3.4**	Fold Factor = 29.8375	
Dermal	1.0E+00	5	100%	3.1E+03	5	15%	80	3.9E+01	22%	**0.8**	[redacted]	

Risks were identified for workers for reproductive/developmental and systemic effects via inhalation and dermal exposures based on quantitative hazard analogue data for the LMW fraction (inhalationMOE= 3.4, dermalMOE=0.8; Benchmark MOE = 100). Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves and a respirator (Fold Factor = 30).

2.6.2 General Population Calculations:

Population/Consumer Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR

	Animal or Human			Human						Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/kg-day Acute Dose Rate (ADR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Multiplier for Susceptible Subpopulations	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Drinking Water (adult)	1.0E+00	5	100%	5.7E-04	7	100%	1.0	22%	**5,774.81**	[redacted]	
Drinking Water (infant	1.0E+00	5	100%	5.7E-04	7	100%	4.2	22%	**1,374.95**		
[redacted]											
Fugitive Air Inhalation	1.0E+00	5	100%	2.1E-04	7	100%	1.0	22%	**15,600.19**		

Risks were not identified for the general population for reproductive/developmental and systemic effects via inhalation exposures based on quantitative hazard analogue data for the LMW fraction (MOE = 15,600; Benchmark MOE = 100).

Risks were not identified for the general population for reproductive/developmental effects via drinking water exposure based on quantitative hazard analogue data for the LMW fraction (adultMOE =5770; infantMOE=1370; Benchmark MOE = 100)

2.6.3 Consumer Calculations:

Risks to consumers were not evaluated because consumer uses were not identified as conditions of use